

RESPONSE AFTER FINAL
U.S. Appln. No. 09/380,579

REMARKS

In paragraph 3, on page 2 of the Office Action, the Examiner maintains the rejection of Claims 9-10 under 35 U.S.C. § 103 as being unpatentable over Slavin et al in view of Ildstad and Zhang et al.

Specifically, the Examiner contends that Slavin et al teaches subjecting the patient to sub-lethal total body irradiation (see column 8, lines 57-67), contrary to Applicants' contention.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

While Slavin et al may teach total body irradiation (TBI), Slavin et al merely discloses TBI as an "unfavorable means" (see the description "Due to its non-selective effects on all of the host's hematopoietic cells and its severe immediate and long-term side effects, TBI is not preferred", in column 8, lines 63-65 in Slavin et al).

Moreover, contrary to the Examiner's contention, Slavin et al does not teach "transplanting of organ into recipient occurs within the same day (one-day protocol)" or an "engraftment rate of 100%", i.e., 100% survival rate, that can be achieved when employing TBI.

The description in Slavin et al cited by the Examiner (column 13, lines 50-67 and column 14, lines 10-15) does not relate to results obtained by employing TBI. TBI was not conducted in Example 14 of Slavin et al, but rather total lymphoid irradiation (TLI) was used, which is fundamentally different from TBI (see the description "non-myeloablative

RESPONSE AFTER FINAL
U.S. Appln. No. 09/380,579

conditioning (e.g., TLI) (day 0)", in column 14, lines 13-14 of Slavin et al. In contrast, TBI is "myeloablative conditioning"). As discussed in detail in the Response dated July 28, 2003, TLI is fundamentally different from TBI.

In Slavin et al, TBI was employed in Examples 10 and 11. However, Slavin et al discloses that a 100% survival rate was not attained in these Examples (see Fig. 4 and Fig. 7). The TBI condition employed in these Examples is 400 cGY, i.e., 4 Gy, which is different from that claimed in the present invention, i.e., at least 6.5 Gy.

As described above, Slavin et al discloses TBI as an unpreferable means, and that a 100% survival rate can not be achieved by employing TBI.

From the teachings of Slavin et al, persons having ordinary skill in the art would not employ TBI, as described in Ildstad, to conduct the "method of inducing immunological tolerance in an organ transplantation recipient" of Slavin et al to achieve a 100% survival rate. A skilled artisan would rather employ TLI, not TBI, of Slavin et al to achieve a 100% survival rate.

As the Examiner states, "The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established science principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination". No such recognition exists in the instant case, because no advantage or expected beneficial result would be produced by a combination of teachings of Slavin et al and Ildstad.

RESPONSE AFTER FINAL

U.S. Appln. No. 09/380,579

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested by Slavin et al alone or when combined with the teachings of Ildstad and Zhang et al, and thus request withdrawal of the Examiner's rejection.

In view of the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at the telephone number listed below on any questions that might arise.

Respectfully submitted,



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